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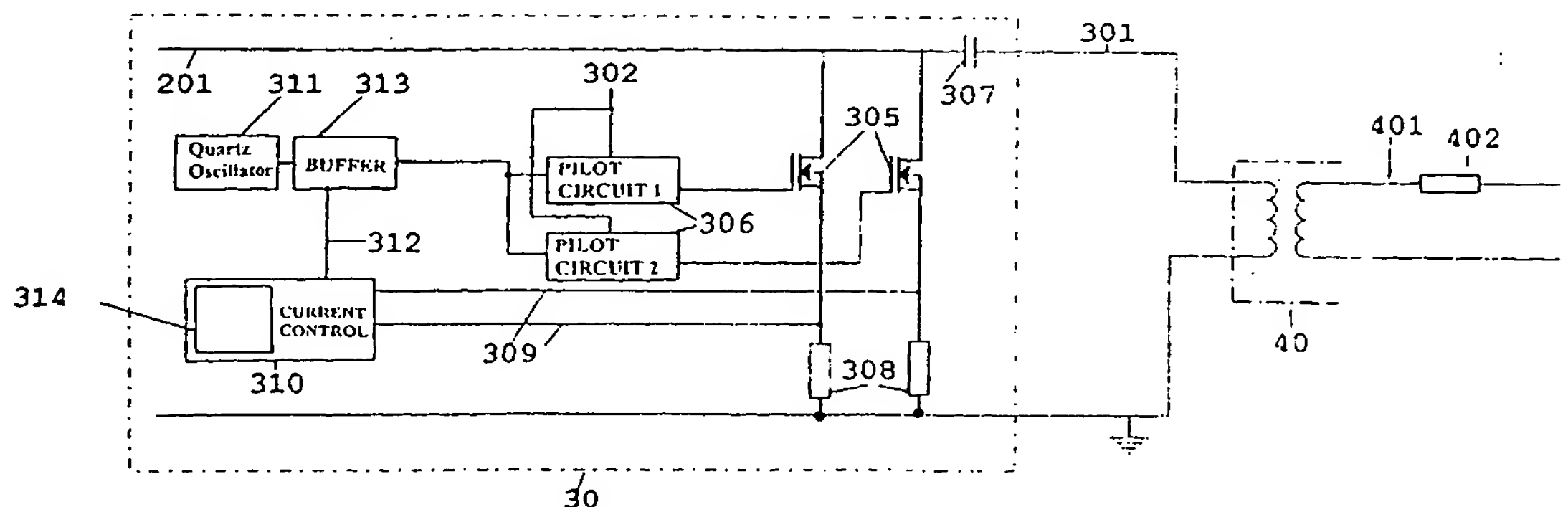
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ning of each regular issue of the PCT Gazette.

(54) Title: ELECTRONIC COAGULATION SCALPEL



(57) Abstract: The invention relates to a method of regulating the power available at the manipulator of an electronic scalpel so as to make said manipulator adapted to be used to obtain blood clotting, said electronic scalpel being of the kind comprising: at least a mains voltage rectifying circuit supplying rectified and direct voltage to at least a radio frequency circuit adapted to emit as output a current carrier signal at a main frequency set by an oscillator, said current signal feeding said manipulator through a radio frequency transformer, wherein said method consists in applying to the manipulator a wave form resulting from the sum of the carrier wave and a modulating wave of such frequency that the energy transmitted to the tissue to be coagulated is such to raise the temperature of the tissue to be coagulated until denaturation of the fibrinogen contained therein is caused and transforming it into fibrin. The invention relates also to the electronic scalpel carrying out such a method.

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ELECTRONIC COAGULATION SCALPEL.

The present invention relates to an electronic scalpel for clotting blood vessels, adapted for surgical applications.

More particularly, as it will be better pointed out in the following description, the invention relates to an electronic scalpel adapted to transfer to the manipulator an electric power and therefore an energy adapted to carry out blood clotting in blood vessels without causing collapse of the vessel wall.

It is well known that blood clotting occurs because a proteinic substance dissolved in the plasma called fibrinogen during blood clotting is organized into a fibrous stable structure called fibrin.

In this way a fibrin mesh is obtained, preventing blood to come out from the blood vessel in which it flows.

Therefore enhancement of organization of fibrinogen into fibrin means to attain the conditions for blood clotting.

Tests have shown that coagulation, that is transformation of fibrinogen into fibrin occurs when to the plasma molecules such a kinetic energy is transferred as to increase their temperature at least up to 63°C. Under these conditions fibrinogen is transformed into fibrin without collapse of the blood vessel.

If a temperature of 80-85°C is exceeded, the vessel collapses and the cells of the blood vessel wall die.

The presently available coagulation techniques carried out with electric scalpels cause a destruction of vessels creating a dead zone and moreover the electric scalpels operate with voltage values at dangerous levels sometimes of thousands of Volts.

The danger of high voltages together with the energy excess transmitted through the electric scalpels, causes destruction of the tissues of blood vessels as above mentioned.

Effectuated tests highlighted that the cells undergoing the action of the electronic scalpel, are not subject to necrotic degenerations when the energy transferred to break the molecular bond of these cells is substantially equal to the energy holding together said molecular bond.

As a matter of fact whenever energy is transferred to a cellular tissue, this causes the tissue molecules to vibrate and the increase of kinetic energy is transformed into a temperature increase of said tissue.

When temperature of the cells goes over 50°C, the cells necrotize and die.

Therefore it is extremely important to operate in such a way that the electronic scalpel carries out the cutting operation without producing heat in the surrounding tissue.

Moreover it was observed that the phenomenon of temperature increase does
5 not occur when and only when the energy transferred to the tissue molecules is equal to the molecule bonding energy.

Indeed in this case the delivered energy is not used to increase the molecule kinetic energy, but only to break the bond joining the molecules to each other.

The object of the invention is to propose a method of regulating an electronic
10 device transmitting the wave form to the manipulator of an electronic scalpel, as well as to carry out said electronic scalpel in such a way to transfer to the tissue area to be coagulated an energy substantially equal to the energy required to obtain a proteinic denaturation transforming the fibrinogen contained in plasma into fibrin without collapse of the blood vessel.

15 Another object is to obtain that the power transferred by the electronic scalpel is such as not to raise the temperature of the surrounding tissues to such high values as to cause collapse of the tissue of the blood vessel.

In other words an object is to obtain that the temperature transmitted by the manipulator of the electronic scalpel to the tissue to be coagulated never
20 exceeds 70-75 °C.

Another object of the invention indeed is to limit as much as possible or even totally prevent collapse of the blood vessels and therefore their destruction because the area no longer supplied with blood naturally dies.

A further objects is to provide an electronic scalpel using relatively low voltages
25 for the coagulation so that the sometimes occurred possibility of intestine perforation is removed even when operating far from it.

The above mentioned objects and others that will be better highlighted in the following are attained by the electronic scalpel of the invention that according to the contents of the main claim is of the kind comprising:

- 30 - a manipulator for coagulation of organic tissues and at least an electrode to close the electric circuit being part of said manipulator;
- a rectifying circuit fed by the mains voltage supplying a rectified, direct or also stabilized voltage to a radio frequency circuit;
- a radio frequency circuit comprising at least an electronic switch fed by said
35 rectified voltage and controlled by a pilot circuit emitting a generally square

current wave of predetermined amplitude and frequency,
wherein said electronic scalpel is characterized in that said radio frequency
circuit has an output of a wave resulting from the combination of a generally
square pulsating carrier wave and a modulating wave, said resulting wave
5 circulating in a wide band resonant circuit at the frequency of said carrier wave.
Advantageously according to the invention at the manipulator one obtains at
generally regular intervals, packets of waves that are resulting from the
combination of a carrier wave with frequency equal to the resonant frequency
of the circuit and a set of harmonics and a modulating wave with suitable
10 frequency.

Each packet of waves available in the manipulator has an amplitude
warranting a power and therefore an energy which is transferred to the cells
involved in the coagulation and causing therein a light heating because the
energy transmitted to said cells is different from the bonding energy of the
15 molecules of said cells. In this way a heating is obtained that can be in the
range of 65-70-75°C but not higher than that, so as to obtain the effect of
denaturation of the fibrinogen into fibrin but not necrosis of the surrounding
cells.

Also advantageously the resonance frequency of the carrier wave is preferably
20 but not necessarily chosen around 4 MHz while the modulating wave may
have the mains frequency, for instance 50 or 60 Hz or a frequency of 20-30
KHz.

The presence of a spectrum of harmonics in the resulting wave causes the
manipulator to transmit a power and therefore an energy to the tissue under
25 coagulation, which is the sum of the different specific energies due to the
various frequencies.

This is particularly important because at each molecule of the cellular tissue to
be coagulated of different nature corresponds an ideal energy to be
transmitted to reach in the present case, the correct temperature allowing
30 transformation of the fibrinogen into fibrin without causing damages to the
other adjacent cells.

According to an embodiment of the invention, the resulting modulated wave is
obtained by enabling and disabling at intermittent intervals a BUFFER circuit
allowing or preventing the crystal oscillator or an eventual frequency
35 synthesizer to transmit its pulsation to the pilot circuit of the electronic switch.

Therefore in this case intermittent pulse trains are obtained, said pulse trains depending upon the frequency by which the microprocessor controlling the BUFFER circuit carries out its enabling and disabling activity.

In another embodiment of the invention the resulting wave is obtained by
5 summing the carrier wave generated at the frequency of the crystal oscillator or an eventual frequency synthesizer and supplied by the pilot circuit to the base of the electronic switch, through a partially rectified mains wave which is connected to the collector of the electronic switch.

The so called basic modulation, namely effected generating pulse trains on the
10 pilot circuit, is particularly used for high power machines while the modulation to the collector is used for low power machines.

Further characteristics and features of the invention will be better highlighted in the following description of a particular embodiment of the invention given as an illustrative but not limiting example and shown in the accompanying sheets
15 of drawings in which:

- Fig. 1 is block diagram of the electronic scalpel of the invention;
- Fig. 2 is a detailed illustration of the radio frequency circuit of the electronic scalpel of Fig. 1; and
- Fig. 3 shows the wave form of the power available at the manipulator of the
20 electronic scalpel referred to the various frequencies.

According to an executive embodiment of the invention, instead of the transformer 11 and the rectifying circuit with filter 20 a stabilized switching AC/DC converter can be used, or a transformer coupled with a rectifying circuit with filter having a stabilized switching DC/DC converter in output.

25 In any case, the voltage 201 outgoing from these rectifying circuits should be direct and stabilized, with a prefixed value preferably comprised for instance between 50 V and 200 V, where the chosen voltage value depends on the utilization of the operating equipment.

Alternatively, for the same intended use of the equipment, the voltage can be
30 different for different functions.

For instance, the feeding voltage can come from two feeders with two different voltage values depending on the bipolar function and the single-polar function of said scalpel, present on the same equipment.

This radio frequency circuit is better shown in Fig. 2.

35 The circuit in this example uses two electronic switches, for instance two

MOSFET.

However, if an electronic scalpel requires higher cutting powers, it is possible to use three or more MOSFET components.

Each MOSFET 305 is controlled by a pilot circuit 306 fed by the voltage 302
5 supplied by a direct voltage stabilized power supply of know type, not shown in the drawings, in which it is possible to regulate the output voltage, which can be also of switching type, to obtain a better efficiency.

The pilot circuit 306 is also regulated by a current control 310 comprising among others a microprocessor 314 which interrupts, at prefixed intervals, the
10 feeding of the pilot circuit so that the resultant wave which goes through the resonant circuit takes the form of a intermittent pulses train, each of them consisting of an amplitude modulated wave.

More particularly the radiofrequency circuit 30 provides that each MOSFET 305 acts as a switch breaking the direct current coming from the output voltage
15 201 of the rectifying circuit 20 and applied to the collector of each MOSFET.

Each pilot circuit 306 emits a unidirectional pulsating not alternated square wave 304 that drives the base of each MOSFET.

The frequency of the pilot circuit 306 is kept constant through a quartz oscillator 311 having an oscillation frequency of 4 MHz connected to a
20 BUFFER 313.

The basic oscillation frequency of 4 MHz, and the higher frequencies too, can be also obtained by a circuit or a specific electronic device, like for instance a frequency synthesizer.

The control of MOSFET 305 occurs through a signal having an oscillation
25 frequency equal to that of the quartz, or of the proper circuit or device, that in case of this example is 4 MHz.

The MOSFET 305 when closed interrupts the current on the leg 301 and when is open it lets the current to pass to the leg 301.

The width of the current wave form at 301 depends on the regulation of the
30 signal 302 connected to the pilot circuit 306.

The regulation of the signal at 302, performed by a potentiometer 303, or for example by a regulator of touch screen type, allows to choose the width of the output wave so as to obtain the power intended for the manipulator 41 of the electronic scalpel according to the operation to be carried out.

35 The following table shows the maximum powers employed in some application

fields, using the scalpel of the invention in cutting operations according to the surgical intervention fields.

TABLE 1

FIELD	POWER OF SCALPEL
Plastic Surgery	Max 90-100 W
Maxillo Facial	Max 90-100 W
Dermatology	50-100 W
ENT	Max 100 W
Gynaecology	Max 100 W
Neurosurgery	Max 25 W
Urology	Max 120 W

From table 1 one can see that the maximum power employed can range from a value lower than 25 Watts, for small dermatologic interventions, up to a maximum of 120 Watts.

To obtain a power adjustment method which is different from the one described in the example, providing for the power adjustment by the variation of the feeding voltage **302** of the drivers piloting the power MOSFETs gates, a still direct and stabilized (by AC/DC converter or by DC/DC converter), but variable for instance from 0 V to 200 V, voltage **201** can be used, while the voltage **302** is maintained steady.

Another possibility is that of using the direct and stabilized voltage **201**, variable for instance from 0 V to 200 V, and the variable voltage **302** too to obtain in this case a power adjustment of mixed type.

According to a possible embodiment of the invention the basic oscillation frequency of 4 MHz is modulated through the intervention of the microprocessor **314** being part of the current control **310** arranging to transfer to the BUFFER circuit an enabling or disabling signal of said circuit with a frequency of 20-30 KHz and with a duty cycle less than 30%.

In this way the BUFFER circuit **310** transmits and breaks the oscillation generated by the oscillator **311** thus generating a pulse train reaching through the pilot circuit **306**, the base of the electronic switch MOSFET **305**.

The resulting wave **301** coming out from the MOSFET switches **305** is therefore a modulated wave whose amplitude is regulated by the power regulator **303**.

According to another embodiment of the invention, a modulated resulting wave may be obtained instead of acting on the interruption of the crystal oscillator **311**, by feeding the electronic switches MOSFET **305** with a voltage **201** which is no longer direct but is a partially rectified pulsating voltage (with single half

wave).

In order to obtain this it is sufficient to modify the rectifying circuit 20 so that the signal 201 comes out from said circuit without the negative half wave and carries only the positive portion of the mains sinusoidal wave.

- 5 Also in this case one obtains an output current 301 from the radio frequency circuit having a resulting wave consisting of a carrier wave at 4 MHz and a modulating wave at 50-60 KHz.

As the output of the radio frequency circuit 30 is connected to the primary of the radio frequency transformer 40, a circulating current 301 is established
10 passing through a resonant circuit at the frequency of 4 MHz, where the capacity and inductance of the resonant circuit are given by the eddy capacity of the MOSFET 305, the capacitor 307 of negligible reactance but acting as lock of the direct component of a voltage 201 and the inductance of the primary circuit of the transformer 40, respectively.

- 15 According to the invention, the resonant circuit on the carrier frequency is of the wide pass-band type so as to let pass even if dampened, at least the second and the third harmonic of the carrier wave relative to the signal 301. Preferably it is desired that the signal 301 has at least the second, the third and the fourth harmonic.

- 20 To obtain a wide pass-band resonant circuit in the embodiment of Fig. 2 a high frequency transformer was used, having a number of turns of the secondary circuit greater than the number of turns of the primary circuit.

This because as it is known, the resonance coefficient Q is given by the formula:

25
$$Q = \omega C_R R_E = 2\pi f C_R R_E =$$

where f is the resonance frequency, C_R is the capacity of the resonant circuit, R_E is the equivalent Resistance of the primary circuit when to the secondary circuit a load is applied consisting for instance of the patient's body to be operated with the electronic scalpel.

- 30 As the equivalent Resistance may be expressed by the formula:

$$R_E = R_C \left(\frac{N_1}{N_2} \right)^2$$

where R_C is the load resistance and N_1 and N_2 is the number of turns of the primary and secondary respectively, one can see that the resonance factor Q may be expressed by the formula:

$$Q = 2\pi f C_R R_C \left(\frac{N_1}{N_2} \right)^2$$

The formula points out that the resonance coefficient decreases when the number of the secondary turns increases relative to that of the primary turns.

The resonance coefficient may also be expressed with the formula

$$Q = \frac{F_R}{B}$$

Where F_R is the resonance frequency and B is the pass-band.

In the case of the invention, when it is desired to widen the pass-band of 4 MHz to 8 MHz, 12 MHz and 16 MHz, in the resonant circuit a transformer is inserted with a suitable number of turns so that the resonance coefficient be lower than 1, preferably between 0,4 and 0,6.

The modulating wave also circulating on the resonant circuit at the frequency of the carrier wave, generates several waves with a frequency out of resonance.

For this reason the resulting wave is rich of waves out of resonant frequency causing the effect to increase the temperature of the blood tissue to be coagulated.

These waves out of resonance frequency may be transferred to the manipulator because the resonance coefficient of the resonant circuit is sufficiently low.

With these characteristics of wide pass-band of the resonant circuit, the secondary current signal of the transformer at **401** takes the form shown in Fig. 3.

Checking the wave form of Fig. 3, one can see that at 4, 8, 12 and 16 MHz there are power peaks that are the interesting ones and are transferred to the scalpel manipulator with the above mentioned effects.

More particularly it was observed that the clotting obtained in the blood tissues is immediate and efficient.

The surrounding tissue does not undergo necrosis because the increase of temperature to 70-75°C is limited to the specific clotting area and does not involve the area of the surrounding tissue.

The transformation of fibrinogen into fibrin is almost immediate.

One can see that the current of signal **401** once the power regulator **302** is set, is controlled through a current control coming from a current sensor **308** arranged after the MOSFET **305**.

The voltage signal **309** coming from the current sensor **308** drives the current control **310** providing to limit through quick comparators controlled by the microprocessor **314**, or by the microprocessor itself, the maximum current **401** acting with the signal **312** on the pilot circuit of the MOSFET.

- 5 In case of low impedance, as the current would rise to very high values, in the circuit there is a current limiter consisting of the inductance **402** limiting the current to the manipulator and hindering the circuit to exceed the maximum admissible current value.

10 The electric circuit is closed through the patient's ohmic load between two electrodes which are the manipulator **41** and a plate electrode **42**.

The plate **42** is preferably covered by a light insulating layer to avoid plate burns to the patient, which are typical of the electronic scalpel.

One can see that the electrode assembly constituted by manipulator **41** and plate **42** may also take the different form of pincers with bipolar operation.

- 15 With the power adjustment method for the clotting electronic scalpel of the invention, it is possible to have an energy available at the manipulator which is substantially equal to the necessary one for having, in the cells interested by the clotting action, a rise in temperature barely sufficient to cause the fibrinogen denaturation, but lower than the temperature which would cause the
20 death of the surrounding tissue cells.

As one can see, said energy dosage is obtained varying the amplitude of the power signal applied to the pilot circuit or to the feeding **201**.

- The consequence of said kind of manipulator energy dosage is to reduce at the least the post-operating stage pains, to considerably reduce the stay
25 time of the patient in hospital after surgery and to consequently reduce hospitalization costs.

- The clotting scalpel of the invention can be used as well without any problem for interventions on patients with pace-maker, because the frequencies used by the scalpel of the invention do not interfere with the correct pace-maker
30 working.

CLAIMS

1) A method of regulating the power available at the manipulator of an electronic scalpel so as to cause said manipulator adapted to be used to obtain blood coagulation, said electronic scalpel being of the kind comprising:

- 5 - at least a rectifying circuit of the mains voltage supplying a rectified and direct voltage to
- at least a radio frequency circuit adapted to emit as output a current carrier signal at a main frequency set by an oscillator, said current signal feeding said manipulator by a radio frequency transformer,
- 10 **characterized by** applying to said manipulator a wave form (301) resulting from the combination of said carrier wave (304) and a modulating wave (201), said resulting wave being of such a frequency that the energy transmitted to the tissue to be coagulated is such to rise the temperature of the tissue to be coagulated until denaturation of the fibrinogen contained in the tissue is
- 15 caused for its transformation into fibrin.

2) The method according to claim 1) **characterized in that** the energy transmitted by the manipulator to the tissue to be coagulated is such that the temperature of the tissue zone in which the coagulation takes place is comprised between 50°C and 75°C.

- 20 3) The method according to claim 1) **characterized in that** the variation of amplitude of the wave form applied to the manipulator is generated by the variation of amplitude of the power signal (302) applied to the pilot circuit or by the variation of the feeding voltage (201).

4) An electronic scalpel to carry out the method of claim 1) of the kind comprising:

- 25 - a manipulator (41) for clotting organic tissues and at least an electrode to close the electric circuit connected thereto;
- a rectifying circuit (20) fed by the mains voltage, supplying a voltage (201) to a radio frequency circuit;
- 30 - a radio frequency circuit (30) comprising at least an electronic switch (305) fed by said voltage (201) and controlled by a pilot circuit (306),
- characterized in that** said radio frequency circuit has as output a resulting wave (301) formed by the combination of a generally square carrier wave (304) and a modulating wave, said resulting wave circulating in a wide band resonant circuit at the frequency of said carrier wave.
- 35

5) The electronic scalpel according to claim 4) **characterized in that** said resonant circuit comprises at least the parasitic capacity of said electronic switch (305) and the inductance of the primary circuit of a radiofrequency transformer feeding said manipulator.

5 6) The electronic scalpel according to claim 4) **characterized in that** the wave form amplitude at the manipulator (41) is variable by means of a regulator (303) which modifies the voltage (302) of the pilot circuit (306).

10 7) The electronic scalpel according to claim 4) **characterized in that** the wave form amplitude at the manipulator (41) is variable by the modification of the rectified and direct voltage (201) which feeds said radiofrequency circuit (30), being maintained constant the voltage (302) feeding the pilot circuit (306) of said at least an electronic switch (305).

15 8) The electronic scalpel according to claim 4) **characterized in that** the wave form amplitude at the manipulator (41) is variable by the modification of the rectified and direct voltage (201) which feeds said radiofrequency circuit (30) and by means of a regulator (303) which modifies the voltage (302) of the pilot circuit (306).

20 9) The electronic scalpel according to claim 4) **characterized in that** said pilot circuit (306) is connected to a control circuit (310) comprising a microprocessor (314) interrupting at predetermined intervals the feeding of said pilot circuit so that the resulting wave passing through the resonant circuit takes the form of a train of intermittent pulses, each consisting of an amplitude modulated wave.

25 10) The electronic scalpel according to claim 4) **characterized in that** said modulating wave is applied to the collector of said electronic switch through a mains rectified voltage wave (201) without the negative half wave.

11) The electronic scalpel according to claim 4) **characterized in that** the carrier wave has the main frequency at 4 MHz.

30 12) The electronic scalpel according to claim 11) **characterized in that** the pulse train of the modulating wave has a frequency of 20-30 KHz.

13) The electronic scalpel according to claim 11) **characterized in that** the modulating wave has a frequency of 50 Hz.

14) The electronic scalpel according to claim 11) **characterized in that** the modulating wave has a frequency of 60 Hz.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/32 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02/053049 A (SENRX INC) 11 July 2002 (2002-07-11) abstract; claim 17; figure 1 -----	4-14
A	US 6 306 134 B1 (GOBLE COLIN CHARLES OWEN ET AL) 23 October 2001 (2001-10-23) column 7, line 24 - column 7, line 67; claim 1 -----	4-14
A	US 4 534 347 A (TAYLOR LEONARD S) 13 August 1985 (1985-08-13) column 4, line 52 - column 5, line 57; claim 1 -----	4-14
A	US 5 011 483 A (SLEISTER DENNIS) 30 April 1991 (1991-04-30) the whole document -----	4-14
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP2004/051021

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 4 517 976 A (OTA TAKAHIRO ET AL) 21 May 1985 (1985-05-21) column 3, line 25 - column 4, line 42; claims 1,9</p> <p>-----</p>	4-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2004/051021

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-3
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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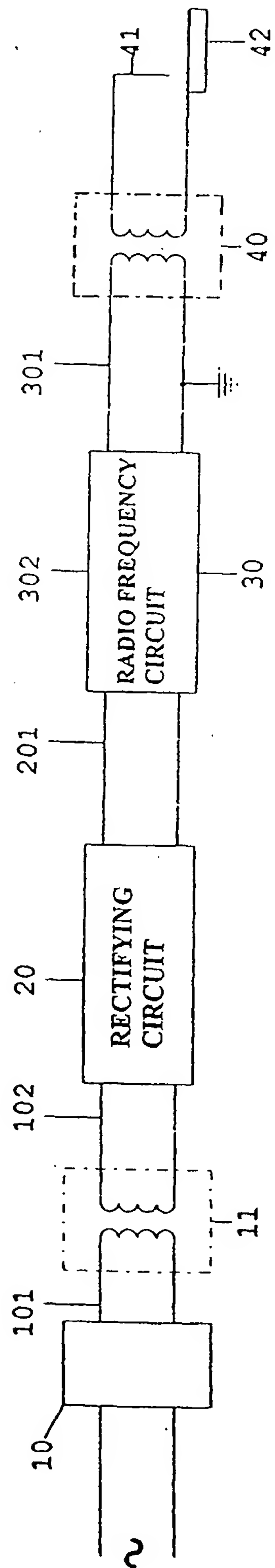


Fig. 1

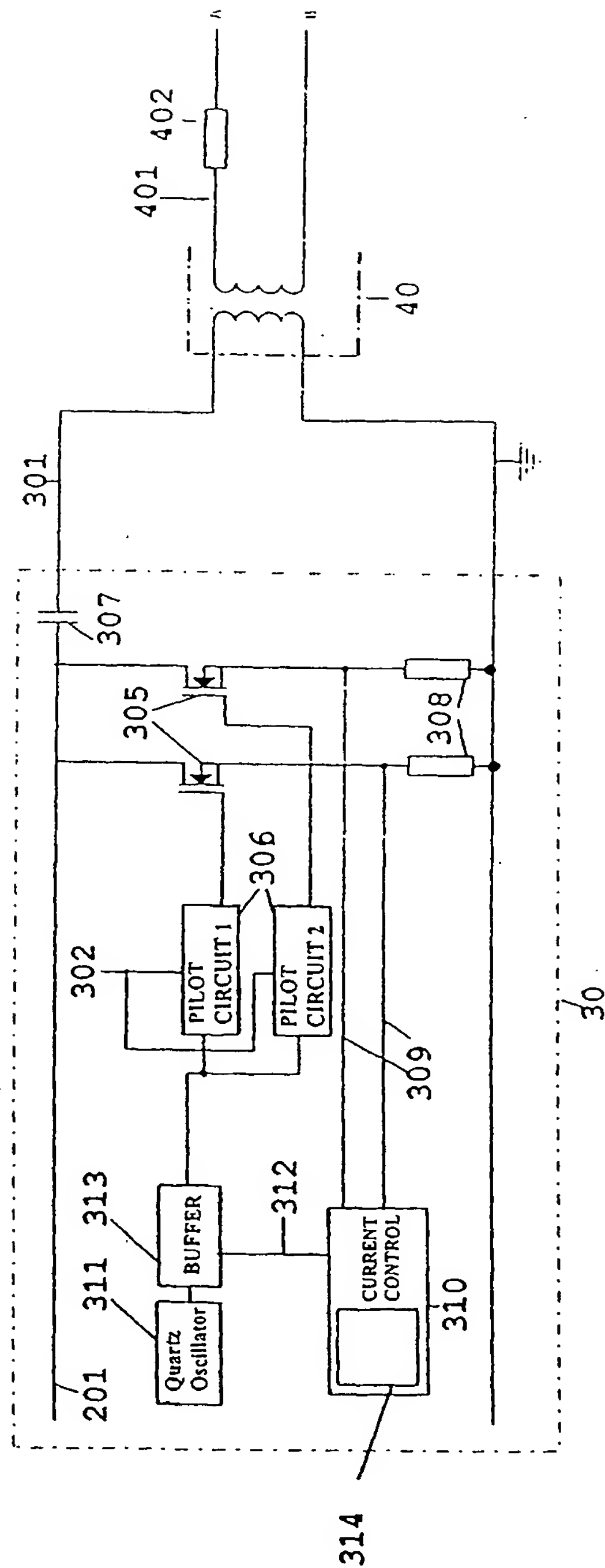


Fig. 2

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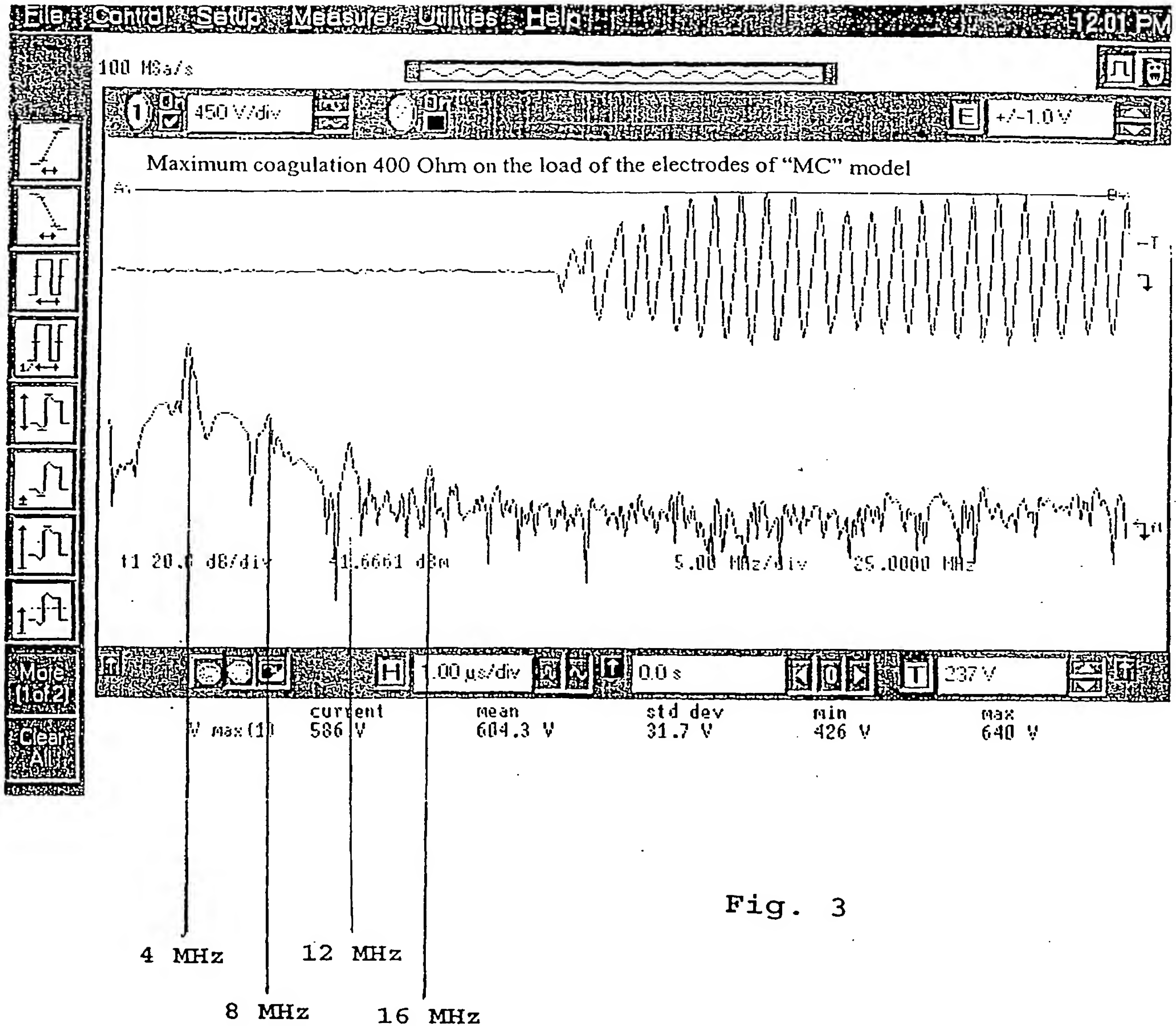


Fig. 3

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